

## **REMARKS**

In the Office Action dated March 11, 2004, claims 1, 6 and 8 were rejected under 35 U.S.C. §103(a) as being unpatentable over European Application 0 347 708. The Examiner stated that the European application teaches that monitoring the end diastolic pressure of a heart provides a clear indicator of the patient's condition, and further teaches the use of a pressure sensor located in the right ventricle. The Examiner stated that the European application does not explicitly state that the device has a signal processor and a timing circuit that defines the start and end of the diastolic phase, but the Examiner considered such circuitry to be obvious because the circuitry in the European application is designed to locate the peak diastolic pressure, as opposed to just the peak pressure.

This rejection is respectfully traversed for the following reasons. The monitoring which takes place for the purpose of detecting tachyarrhythmia in the circuitry disclosed in the European application is concerned exclusively with identifying and monitoring right heart end diastolic pressure, as stated at column 3, line 47. This is why, as explained in the paragraph beginning at column 5, line 35 of the European application, the circuitry disclosed therein is designed to detect the end diastolic pressure (EDP) because this is stated to provide the greatest positive change in percentage during ventricular tachycardia. For this purpose, as stated in the paragraph beginning at column 6, line 7 of the European application, a pressure sensor and peak detector are used. It is further stated at the end of that paragraph that the mean pressure or volume is obtained by passing the raw pressure or volume signal through a low-pass filter.

As the Examiner has noted, there is no teaching in the European application to employ a timing unit to identify, from the right ventricular pressure signal, a beginning and an end of the diastolic phase. The peak pressure that is detected in the European application happens to occur at the end of the diastolic phase, however, the European application does not provide any teachings that the *timing* of this peak is of any importance for actually indicating or designating an end of the diastolic phase. It is only important in the context of the European application that this peak value be identified and measured, and it is merely a coincidence that this peak value happens to occur at the end of the diastolic phase. Therefore, even though this peak value is measured, there is no teaching in the European application that the time that it occurs is of any importance, or is even noted.

Moreover, there is no teaching anywhere in the European application to take any steps to identify the *beginning* of the diastolic phase. This is understandable because, as noted above, the only characteristic within the diastolic phase itself is the aforementioned end peak pressure. The aforementioned statement at the end of the paragraph beginning at column 6, line 7 of the European application refers only to mean pressure or volume, and is not limited to a determination of diastolic pressure or volume, i.e., pressure or volume occurring only in the diastolic phase, as set forth in claim 1 of the present application. The pressure or volume referred to at the end of the paragraph beginning at column 6, line 7 of the European application must mean the average pressure in both the systolic and diastolic phases, since there is no teaching in the European application as to how the beginning of the diastolic phase could be identified. Identifying both the beginning and the end of the diastolic phase is a necessary condition for being able to determine the average

pressure or volume in that phase. In the absence of any teaching in the European application to identify the beginning of the diastolic phase, the mean or average pressure or volume referred to on the European application cannot mean the average diastolic pressure or the average diastolic volume.

There is one location in the European application, namely at column 4, lines 21-23 wherein a reference is made to monitoring "mean and/or diastolic pressure/volumes." Applicants submit that a person of ordinary skill in the field of cardiac pressure measurement would recognize that this is merely a generalized statement, and it is not consistent with the explicit enumeration of the characteristics that are monitored set forth in column 4, lines 2-9 of the European application. None of these specifically enumerated measurements at that location refer to an average or mean diastolic pressure. Moreover, as noted above, if there is no capability of identifying the beginning of the diastolic phase, it is impossible to measure or monitor the average diastolic pressure. A person of ordinary skill in the field of cardiac pressure measurement reading the European application would immediately recognize that there is no such detection of the beginning of the diastolic phase disclosed in that reference, and therefore would understand the aforementioned language at column 4, lines 21-23 as being a generalized statement encompassing the specifically enumerated characteristics that are identified earlier at column 4, lines 2-9.

Consistent with this discussion, independent claim 1 has been amended to explicitly state that the right ventricular pressure is identified during the *entire* diastolic phase of the heart cycle, and to further state that this is defined by the beginning and the end of the diastolic phase that are identified earlier in the claim.

The most that can be said of the European application is that it teaches measuring or monitoring the end diastolic peak pressure and the mean ventricular pressure or volume, but there is no teaching in that reference that the right ventricular pressure during the entire diastolic phase should be monitored or identified, and there is no teaching in the European application of circuitry that could accomplish that result.

Claim 1, therefore, would not have been obvious to a person of ordinary skill in the field of cardiac pressure measurement based on the teachings of the European application. Claims 6 and 8 add further structure to the non-obvious combination of claim 1, and therefore would not have been obvious to a person of ordinary skill for the same reasons.

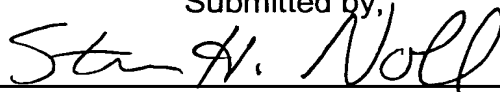
Claim 2 was rejected under 35 U.S.C. §103(a) as being unpatentable over the European application, further in view of Kieval. Claim 7 was rejected under 35 U.S.C. §103(a) as being unpatentable over the European application, further in view of Noren. Claims 2-5 were rejected under 35 U.S.C. §103(a) as being unpatentable over the European application, further in view of Carney.

In view of the fact that all of these claims depend from independent claim 1, and in view of the above arguments that the European application does not provide teachings that would render the subject matter of claim 1 as being obvious, Applicants submit that even if the teachings of the European application were modified by or combined with the teachings of one or more of the secondary references, the subject matter of the respective dependent claims still would not result.

All claims of the application are therefore submitted to be in condition for allowance, and early reconsideration of the application is respectfully requested.

Editorial changes have been made in the specification to correct certain grammatical errors.

Submitted by,



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